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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,037	06/25/2003	Kees Jalink	66784-015	6398

7590 03/14/2006  
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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 03/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/607,037		JALINK, KEES	
	<b>Examiner</b>		<b>Art Unit</b>	
	Rosanne Kosson		1653	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7, drawn to a phosphatidylinositol 4,5-bisphosphate (PIP2) indicator comprising two proteins, one with a pleckstrin homology domain and donor fluorescent domain, the other with a pleckstrin homology domain and an acceptor fluorescent domain, classified in class 530, subclass 350.
- II. Claims 8-14, drawn to a nucleic acid kit comprising polynucleotides that encode two proteins, one with a pleckstrin homology domain and donor fluorescent domain, the other with a pleckstrin homology domain and an acceptor fluorescent domain, classified in class 536, subclass 23.4.
- III. Claims 15-21, drawn to a method of indicating PIP2 levels in a cell, classified in class 435, subclass 7.1.
- IV. Claims 22-30, drawn to a method of identifying a compound that modulates PIP2 levels in a cell, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

The DNA of group II is related to the protein of group I by virtue of the fact that the DNA codes for the proteins. The DNA molecules have utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, because the DNA molecules encode the claimed proteins, the two groups are distinct inventions because the protein products can be made by other and materially distinct processes, such as purification from natural sources or by chemical synthesis. Further, the DNA molecules

can be used for processes other than the production of protein, such as nucleic acid hybridization assays. Therefore, these inventions are patentably distinct.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the product of Group I can be used in the method of Group III, a method of indicating PIP2 levels in a cell, or Group IV, a method of identifying modulators of PIP2 levels in a cell. Additionally, because pleckstrin homology domains bind to a number of ligands, such as phosphorylated serine and threonine residues, GTP-ase activating proteins, phospholipases, cytoskeletal proteins, and the beta/gamma subunit of G proteins, as well as to PIP2 (see Abstract of Yoon et al., "Solution structure of a pleckstrin-homology domain," Nature 369:672-675, 1994, and Fesik, "Pleckstrin, N terminal pleckstrin homology domain," <http://www-nmr.cabm.rutgers.edu/photogallery/structures/html/page34.html>, printed from the Internet on February 13, 2006), the proteins of Group I may be used in a variety of methods in which the binding of these proteins to one of their ligands creates a measurable label of the amount of ligand present. Therefore, these inventions are patentably distinct.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, as discussed above, the product of

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Group I can be used in the method of Group III, a method of indicating PIP2 levels in a cell, or of Group IV, a method of identifying modulators of PIP2 levels in a cell, as well in a number of other methods in which it is desired to measure the amount of ligand of a pleckstrin homology domain. Therefore, these inventions are patentably distinct.

Inventions II and III, as well as inventions II and IV are related in that the protein encoded by the DNA molecules of Group II is used in the methods of Groups III and IV. But, the DNA molecules are not used in these methods and are not required to practice these methods. Therefore, Groups II and III and Groups II and IV are patentably distinct.

Inventions III and IV are related in that each method uses the proteins of Group I. But each method has different steps, a different function and a different effect. In Group III, the FRET between the two protein is quantified as measure of the amount of PIP2. In Group IV, compounds that enhance or inhibit the interactions of the two proteins are identified. Therefore, these inventions are patentably distinct.

Additionally, the searches for any one group are not required for and are not coextensive with the searches for any other group, thereby creating an undue burden of search and examination. The results from a search of each of these groups have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement. Further, the different groups have each acquired a separate status in the art, as shown in part by their different classifications.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is clearly proper.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner, Art Unit 1653

rk/2006-02-13



ROBERT A. WAX  
PRIMARY EXAMINER